Section 14: 510(k) Summary

OCT 1 6 2008

K080793

FLEXICATH Ltd.

510(K) SUMMARY

for FirmGrip™ Peripherally Inserted Catheter Device

Date Prepared: 28 February, 2008

510(k) owner name:

Company name:	Flexicath Ltd.
Address:	120 Yigal Alon St. California Building, Suite 107 Tel Aviv 67443 ISRAEL
Tel.:	+972 (4) 8500076
Fax:	+972 (4) 8500684
E-mail:	mail@flexicath.com

Contact person:

Name:	Tali Hazan
Address:	Ramot-Naftali, 13830 ISRAEL
Tel.:	+972-50-5292304
Fax:	+972-151508963806
E-mail:	tali@012.net.il

Device Name:

Common or usual name: Peripherally Inserted Catheter
Proprietary/Trade name: FirmGrip™ - Peripherally Inserted Catheter Device

Classification name: FirmGrip™ has been classified as **Class II** device under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	FOZ	880.5200	General Hospital

Predicate Device:

Modified FirmGrip™ - Peripherally Inserted Catheter Device is substantially equivalent to the original FirmGrip™ Peripherally Inserted Catheter Device, cleared under 510(k) number K063363.

Device description:

The FirmGrip™ peripherally inserted catheter includes a typical midline catheter encapsulated in a specially designed protective sleeve, to produce a self-contained clean catheter insertion field. The catheter contains a stiffening guidewire for additional contribution to ease of insertion and for catheter's internal air volume reduction.
Both the catheter and guidewire remain protected throughout the entire catheter insertion procedure and is not exposed to the outer environment or to any hand contact. The protective sleeve back side is closed with a Tortuous Path Disc (TP Disc) which closed it and provides additional protection. Being the catheter protected by the sleeve, may save the need of using a sterile sheet since the sleeve may replace it. The protective sleeve enables manipulation and insertion of the catheter without interfering the protective sleeve's internal clean field. Once the catheter is properly placed in the blood vessel, both protective sleeve and the guidewire are removed and discarded.
The FirmGrip™ is packed in an individual sterile pack and is sterilized by EtO.

A needle assembly unit contains a specially designed adapter, called "PeelGuard", and a PeelAway needle introducer is supplied with the FirmGrip™ or separately. The needle assembly unit has its own individual package and is sterilized by EtO as well.

The operation mechanism for the modified device is the same as the original device. The protective sleeve's handgrip portion, in its front side, has an accordion-shape which helps to promote the catheter with each intermittent grasping and pushing it forward.
Once both the sleeve and the wire are removed, the catheter remains inside the vein. The catheter luer connector and a short portion of the catheter remain outside of the body and used as an access port for the medical treatment. The soft materials used for the catheter and PeelGuard make the connections more flexible, easy to use for the medical staff and more convenient for the patient.

Intended use:

The FirmGrip™ Peripherally Inserted Catheter Device is intended for use in patients requiring repeated access to the peripheral venous system for infusion or injection intravenous therapies and/or blood sampling.

Technological characteristics and Substantial Equivalence:

The modified FirmGrip™ - Peripherally Inserted Catheter is substantially equivalent the original FirmGrip™ that was previously cleared under 510(k) number K063363.
Both new and predicate devices have the same indication for use, same basic shape, design and characteristics. All changes that differs the modified device from the original (predicate) device were fully evaluated.

The modifications performed do not affecting the device's intended us and do not alter the device's fundamental scientific technology.
New device verification and validation tests showed that it is as safe and as effective as the predicate device.

None clinical performance data:

Tests results are supporting all labeling claims and substantial equivalency.
The modified device was tested with according to Flexicath's legally marketed device specification and all acceptance criteria were met.

Conclusions:

The evaluation of Flexicath's FirmGrip - Peripherally Inserted Catheter Device non-clinical tests, demonstrates that the device is as safe and as effective as the predicate device. Therefore, we believe it is substantially equivalent to Flexicath's legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2008

Ms. Tali Hazan
Regulatory Affairs Advisor
Flexicath Limited
120 Yigal Alon Street
California Building, Suite 107
Tel Aviv 67443
ISRAEL

Re: K080793
Trade/Device Name: FirmGrip™ Peripherally Inserted Catheter Device
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: August 6, 2008
Received: August 12, 2008

Dear Ms. Hazan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

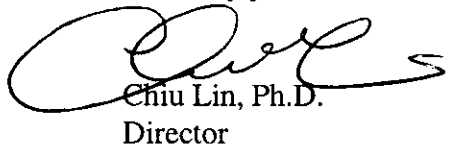
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FLEXICATH Ltd.

Section 4: Indication For Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080793

Device Name: FirmGrip™ Peripherally Inserted Catheter Device

Indications for use: The FirmGrip™ Peripherally Inserted Catheter Device is intended for use in patients requiring repeated access to the peripheral venous system for infusion or injection intravenous therapies and/or blood sampling.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080793

(Posted November 13, 2003)